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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
PADGETT, MARIANNE L	
ART UNIT	**PAPER NUMBER**
1762	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/687,070	HANSEN, HENRIK	
	Examiner	Art Unit	
	Marianne L. Padgett	1762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17,20-31,33 and 38-41* is/are pending in the application.

4a) Of the above claim(s) *17* is/are withdrawn from consideration.

5)☒ Claim(s) *38-39* is/are allowed.

6)☒ Claim(s) *20-31,33,40 and 41* is/are rejected.

7)☐ Claim(s) *31* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/14/2007 has been entered.

Applicant's amendment has put the limitation of dependent claim 32 into independent claim 20, canceled claims 35 & 37, which were previously objected to as containing allowable subject matter, and presented you claims 38 & 39 which contain all the limitations of previous independent claim 20, plus the subject matter indicate the allowable therewith.

The examiner notes that claim 17 directed to withdrawn subject matter, and dependent on the canceled claim 1, remains pending.

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 20-30, 33-34 & 40-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pacetti et al (6,355,058 B1), in view of Escallon et al (4,749,125) as applied/discuss in sections 5 & 3 of the 5/6/04 & 3/29/05 actions, and further in view of Leidner et al.(6,056,993) or Shikani et al. (5,695,458), as applied in sections 4 & 3 of the actions mailed 12/21/2005 & 12/13/2006.

Independent claim 20 has been amended to recite "the polymeric material is about 1 to about 15 weight % of the coating formulation", however it is noted that "polymeric material" is completely generic, encompassing the smallest polymeric monomer to the largest polymerized molecule, including both purely organic & polymeric molecules such as silicone which contain inorganic atoms, such that the claim

proportions would not have the same significance to all polymeric materials. With respect to the references applied for discussion of useful electrostaticspray in compositions, it is noted that Leidner et al. on column 9, lines 7- 23, particularly 17-23 discussed general guidelines for compositions of the solution comprising about 80 parts by weight of organic solvent per 10-160 parts by weight of their polymers, which gives about (10/(80+10)) = 11 % to (160/(80+160)) = 67 %, which overlaps with applicant's claimed range, especially considering Leidner et al.'s preferred solvent or halogen aided alkanes inclusive of trichloroethane as claimed. Thus in accordance with previous discussion, this specifically claimed parameter is not considered to provide patentable significance, as it overlaps with known parameter ranges for analogous materials & would have been dependent on specific polymers employed in order to draw provide desirable solution viscosity & the like, which would have been expected to be determined by routine experimentation for particular materials.

As noted in the 3/29/05 action, Pacetti et al. in view Escallon et al. do not teach the use of the claims solvents, tetrahydrofuran or chloroform or toluene or acetone or isooctane or trichloroethane, in their electrostatically sprayed polymeric solutions, however on further review of the prior art it has been found that Leidner et al. teach electrostatically spraying polymer solutions, where the polymers may be silicone, high density polyethylene, polyurethane, polyester, polycarbonate,...or combinations thereof, with teachings on how to choose an organic solvent for a particular solution, wherefore the preferred silicone polymers, trichloroethane is the preferred solvent with halogenated alkanes generically taught as preferred, which is suggestive of chloroform, i.e. trichloromethane. Leidner et al. also optionally teach forming the composition such that it contains therapeutic ingredients, i.e. the equivalent of applicants' biologically active material. The examiner notes that the wide variety of both polymeric materials & therapeutic ingredients will contain numerous combinations were the melting point of whichever polymer is chosen is lower than many of the decomposition temperatures of suggested ingredients, especially as "biologically active material" is inclusive of inorganic materials that are biologically active and have

much higher decomposition temperatures than the melting points of many polymers. In Leidner et al., see the abstract; figure 1; col. 8, line 27-col. 9, line 56+; col. 10, lines 15-30 & 43-60, noting further only from her and polymer teachings including polyethylene glycol (PEG), poly (methylvinyl ether), polyacrylic acid, esters of poly (meth) acrylic acid, etc.; and col. 14, lines 42-67.

Leidner et al.'s technique is for actually making tubular prosthesis via deposition on mandrel, instead of merely coating them, however given that Pacetti et al. is coating **stents**, i.e. tubular prosthesis, via liquid electrostatic spraying that may include polymer binders of silicone or polycarbonate urethanes or polyethylene, etc., it would've been obvious for one of ordinary skill in the art to apply Leidner et al.'s teachings on solvents for electrospraying like materials for analogous purposes to the similar materials of Pacetti et al., particularly the use of halogenated alkanes, such as trichloroethane, when spraying silicones, to provide demonstrated effective solutions for the taught spraying technique, as taught in the combination of Pacetti and Escallon.

Alternately, Shikani et al. (458) teaches spraying polymer iodine coatings on medical products for disinfectant purposes, where successfully coated medical devices include catheters, tubes related to blood transfusions, needles and scalpel blades, all of which fit the criteria of being adapted for exposure to body tissue of the patient. Suggested polymers include polyethylene, silicone, polyvinyl chloride, polyethylene phthalate or polyesters, polypropylene, rubber, polyurethane, ethylene vinyl acetate, nylon, polycarbonate, cellulose esters, polystyrene, etc., where it is taught that polymers must be soluble in organic solvent solutions with useful organic solvents taught to include ethanol, aliphatic ketones (i.e. dimethyl ketone), tetrahydrofuran (THF) and chlorinated hydrocarbons. Various exemplary proportions include "1 %w/v solution of segmented polyurethane... in THF...", etc. or the general teaching that "compositions may contain up to about 10% of the film forming inert polymer and up to about 10% of the polymeric iodophor." A specific exemplary composition to be sprayed was polyurethane in THF with iodine, which is an inorganic biologically active agent. In Shikani et al. (458), see figures 1-2; col. 2,

lines 1-14, including incorporation by reference of Domb et al. (5,344,411) & Shikani et al. (5,437,656) with further discussion of coating medical devices; col. 3, lines 33-44 & 63-col. 4, line 2; col. 6, line 45-col. 7 lines 10, 25-38 & 49-col. 8, line 2; and col. 9, line 33-40.

Given the teachings of Shikani et al. (458) on effective solutions for spraying biologically affecting polymer coatings using organic solvents, such as THF or chlorinated hydrocarbons, it would have been obvious to one of ordinary skill in the art to employ taught affective solvents for such polymer solutions for the analogous liquid polymer compositions for electrostatic spraying taught in Pacetti et al., who is silent on the topic of claimed solvents, because effectiveness for overlapping polymers, such as polyurethanes, is demonstrated for sufficiently analogous purposes thus providing an expectation of the effectiveness of these taught and claimed solvents in the electrostatic spraying process of the combination of Pacetti and Escallon.

As previously noted it is not necessary for all the references to apply their coatings to the same kind of devices, i.e. all claims are requiring implantable medical devices to be the substrates, however while enduse will be important to techniques chosen, is not the only factor which is important in choosing a deposition technique, nor is it the only place that can provide teachings that are applicable to a deposition technique, such as electrostatic spraying, where the matrix material being sprayed provides characteristic requirements for the technique employed, which would have been expected to be applicable across different enduses. The patent to Escallon et al. is teaching a generic electrostaticspray process, which is generally useful for many applications & applicable to flowable materials, including biological compounds, polymeric compounds, etc., such that the reference's not mentioning a specific enduse does not exclude it from applicability to that enduse, especially considering Pacetti et al., which is applicable to a specific enduse, but is generally teaching the possibility of using various deposition (spray) techniques, inclusive of electrostaticspray, hence it would've been incumbent on one of ordinary skill in the art to review prior art electrostaticspray techniques, such as those of Escallon on et al., with the intent to use

them in the process of the primary reference, should they meet criteria commensurate with the process, which they have been shown to do. Choice of specific solution materials, would have been expected to be optimized for particular enduse, and not provide patentable significance to the process per se unless they were not known to be used in such an electrostaticspray process &/or enduse, or would have been expected to produce different results in the instant invention, i.e. provide unobvious results. Such has not been demonstrated for the rejected claims specific solvents with more generic polymeric coating materials.

4. Claims 20-30, 32-33 & 40-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bowlin et al. (2002/0081732 A1), noting that the filing date is October 18, 2001 with provisional applications 60/241,008 filed 10/18/2000 & 60/270,118 filed 2/22/2001, where (008) incorporates by reference SN 09/654,517 (abandoned, not IFW), SN 09/512,081(abandoned, not IFW) and 09/386273 (now PN 6,592,623), as applied in sections 5 & 4 of the actions mailed 12/21/2005 & 12/13/2006.

Bowlin et al. (2002/0081732 A1) teach **electrospraying** or electrospinning, where the substrate or target, which is being deposited on may be grounded and charge is supplied to the solution in its source chamber, where compositions are inclusive of claimed polymers, such as polylactic acid (PLA) or poly (ethylene-co-vinyl acetate) used with chloroform, with teachings on importance of and effective choice of solvent (abstract; figures 1-2 & 8; [0067]; [0070- 75, especially 73]; [0082-92]; [0102- 0110, especially 102-103, 106-107 & 110]; [0199-200] concerning preparing implants, including vascular, which would suggest stents to one of what Neary skill), however for this reference to be prior art the provisional documents must supply appropriate support. In the **(008) document**, see figure 1; page 1-3; page 7 top; and claims 21-27, which supply the above relevant information, except for specific solvents, having only general teachings on the needs when selecting solvents. The **(008) document** specifically states that the taught "electric processing has many potential applications in biological sciences. One... is the use of electric processing (electrospinning, electro-aerosol, electrospray) for the delivery of..." (page 1), where

any one of ordinary skill in the art would recognize that both electro**aerosol** & electro**spray** inherently form droplets, contrary to applicant's apparent assertions. Page 2 of (088) discusses creating matrix material for insertion into the body or sub-dermal domain via electro-processing, such as electrospinning, with discussion of solvent carriers, polymers etc., where the paragraph bridging pages 2-3, at the top of page 3, specifically teaches that these polymer superstructure is could also be fabricated by electrospraying, thus explicitly relating all the teachings for a electrospinning to electrospraying. It is further noted that PN 6,592,623 **incorporated-by-reference** further illustrates relevant apparatus configurations in figures 2A, 2B & 7; col. 4-6 and in example 1 on col. 12-13, discusses the polymers PLA, polyglycolic acid (PGA) & copolymer of ethylene and vinyl acetate dissolves in solution with dichloromethane to be used for electrospinning, where proportions are given in g/ml, which the examiner cannot convert to weight %. What information the two abandon applications supply, is not known at this time. Hence, while Bowlin et al. (732 A1) teach the claimed chloroform used in a claimed process, their support documents as available fall short of these, in that the chloroform is indicated to be used with the electrospinning, but no specific examples of solvent used with electrospraying is provided. **However, it would've been obvious to one of ordinary skill in the art as the provisional (008) document teaches similar considerations in choice of solvent for both electrospraying and electrospinning,** as well as teaching that electrospraying can be used in combination with electrospinning or by itself, to employ the taught polymer-chloroform compositions in the taught electrospraying, as well as in the exemplified electrospinning, as the more general teachings suggest that such would have been applicable. As this concept has been argued as obvious over what he is in the priority document, and applicant has provided no reasons to the contrary, Bowlin et al. (732) cannot properly be excluded as prior art on the basis of not having what was argued as obvious!

Specifically claimed parameters not set forth in the teachings of Bowlin et al. would have been expected to be determined be a routine experimentation, with variations expected due to particular choice

of compositions including varying combinations of polymers, solvents and therapeutic agents, hence expected to be within or overlapping with claimed ranges. While they implantable enduses do not specifically state that they are stents, the general categories suggested are inclusive of stents, and would have been obvious to any one of ordinary skill in the art that this typical conventional use our configuration would have been effectively produced by the process of Bowlin et al.

5. Applicant's arguments filed 6/21/2006, and partially discussed above have been fully considered but they are not persuasive.

In applicant's discussion concerning Leidner et al. they state "Leidner also does not disclose or suggest creating droplets of the electrically charged coding formulation, and deposited the droplets of the coding formulation...", however the examiner is unclear what applicant is proposing that Leidner is electrostatically spraying, when they electrostatically spray compositions indistinguishable from those claimed by applicant, especially considering that the act of sprain liquid solution will inherit form droplets, that the process is electrostatically spraying would tell any one of ordinary skill in the art that these droplets are charged, hence Leidner et al. not explicitly describing the shape of the electrostatically spray solution as being droplets, does not preclude that solution from forming droplets.

Applicant's arguments appear to imply that it is necessary for a ternary reference to have all the components of the claims, even the components for which it was not applied, this is not the case. However with respect to Shikani et al., where applicant asserts that this reference teaches away from providing implantable medical devices, it is suggested that column 2, lines 1-4, which states "The present inventors had successfully coated medical devices from different materials. They had successfully coded venous catheters and bladder-Foley catheters, containing polymers and iodine; demonstrating that the iodine is released in a sustained fashion over prolonged periods of time...", thus explicitly discussing coded articles in contact with body tissues of the patient, hence in no way teaching away as asserted by applicant. All examples in a reference need not be to the same range of enduses recited in the claims.

6. Claims 31 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations (specific polymeric materials employed) of the base claim and any intervening claims.

Claims 38-39 would appear to be allowable at this time.

7. Other art of interest to the electrostaticspraying art includes Akhave et al. (7,132,159 B1), who electrostaticspray discrete droplets of polymeric solutions, usable for purposes such as a medical adhesive. Also of interest, but not prior art are Kerrigan (2006/0126431 A1); Feng et al. (2007/0048452 A1); Tochterman et al. (2007/0141232 A1); Chappa (2006/0088653 A1); Warner et al. (2006/0088567 A1); O'Connor et al. (2006/0198942 A1); & Schachter et al. (2007/0077435 A1), all directed towards electrostaticspraying or related techniques for medical devices.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne L. Padgett whose telephone number is (571) 272-1425. The examiner can normally be reached on M-F from about 8:30 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Timothy Meeks, can be reached at (571) 272-1423. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MLP/dictation software

6/23/2007

MARIANNE PADGETT
PRIMARY EXAMINER